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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,604	06/26/2002	Alex Bollen	B45168	2758

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EXAMINER	
FIELD, TAMMY K	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,604	BOLLEN ET AL.	
	Examiner	Art Unit	
	Tammy K. Field	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-34,47,61-65 and 72-76* is/are pending in the application.

4a) Of the above claim(s) *35-46,48-60,66-71,77 and 78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-34,47,61-65 and 72-76* is/are rejected.

7)☒ Claim(s) *61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/20/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Election/Restrictions

1. Applicant's election with traverse of Group I, (Claims 30-34, 47, 61-65, and 72-76) and species election of SEQ ID NO: 42 received April 16, 2004 are acknowledged. The traversal is on the ground(s) that the inventions are not independent. This is not found persuasive because the grouping of inventions was based according to 371 practice of Lack of Unity determination under PCT Rule 13.1 and under PCT Rule 13.2.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 30-34, 47, 61-65, and 72-76 as they read on SEQ ID NO: 42 are presently under examination.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to UK Application 9828217.1 and that a certified copy was filed June 20, 2001 with the instant application. However, it appears that SEQ ID NO: 42 was not disclosed in the UK Application. Therefore, the date of December 21, 1999 of PCT/EP99/10297 will be used for purposes of prior art.

Information Disclosure Statement

4. The information disclosure statement(s) filed June 20, 2001 has been considered. An initialed copy is enclosed.

Claim Objections

5. Claim 61 is objected to because of the following informalities:

a. The wording of "...a polypeptide as claimed claim 30..." is confusing.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 30-34, 47, 61-65, and 72-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompass an isolated polypeptide, which has at least 75% identity to SEQ ID NO: 42 and further comprising SEQ ID NO: 42, and fragment thereof comprising an epitope, more specifically an immunogenic epitope. Subsequent claims encompass a process for producing the polypeptide, methods of diagnosing a *Bordetella pertussis* infection comprising identifying the polypeptide or antibody that is immunospecific for the polypeptide in a biological sample from an animal, and kits for diagnosing infection with *B. pertussis* bacteria in a human comprising the polypeptide.

The specification disclose the polypeptide of SEQ ID NO: 42 in the sequence listing. The specification further disclose reference to "...polypeptides comprising the amino acid sequence encoded by the genes defined in Tables 2 and 3..." at page 16, lines 8-9. The specification also disclose general methods of polycolonal and monoclonal antibody production at page 29, line 13 - page 30, line 25. The specification further disclose making and amplifying polypeptides in Example 1 at page 33.

The specification fails to identify SEQ ID NO: 42 in relation to genes at Table 2 and 3. Further, how are the proteins at page 11, lines 25-30 related to SEQ ID NO: 42? What does "...depending on the particular sequence)." at page 17, line 5 mean in relation to SEQ ID NO: 42? How is SEQ ID NO: 42 related to the *B. pertussis* BcrD deduced amino acid sequence at page 35, lines 7-11, and more specifically at Fig. 2? Further, how is SEQ ID NO: 42 related to Tables 2 and 3? Further, how is a phage displaying an antibody in a kit used in the production of antibodies at page 25, line 5?

Further, the specification only disclose general concepts of diagnostic assays, antibody, and various kit components that **may** (emphasis added) provide a diagnostic tool for diagnosing *B. pertussis* at page 24, line 17-page 25, line 12. Further, the specification only disclose **diagnosis** (emphasis added) of *B. pertussis* bacterial infection by assaying infected lung tissue and plating on BG agar, and growth of *B. pertussis* in liquid culture at page 41, line 27 - page 42, line 6. There also appears to be no working examples of diagnosing *B. pertussis* using the polypeptide of SEQ ID NO: 42.

Without further direction or guidance of the exact relevance of SEQ ID NO: 42 claimed in the instant invention, how to use the polypeptide of SEQ ID NO: 42, working examples disclosing the diagnostic effect(s) of the polypeptide or fragment(s) of SEQ ID NO: 42, and antibody production and/or reaction(s) against SEQ ID: 42, there would be undo experimentation required for one of skill in the art to make and/or use the invention as claimed.

7. Claims 61-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the claims is not as precise as the subject matter permits such that one may reasonably know the metes and bounds of the claims and bounds of the claimed subject matter. The claims are indefinite in the recitation of "identifying a polypeptide" and "antibody that is immunospecific for said polypeptide" because it is unclear from the specification what applicant intends. Clarification is required in order to overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 30-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith, S. *et al.* 1996. (J. Clin. Microbiol. 34(2) : 429-430).

The claims are drawn to an isolated polypeptide comprising an amino acid sequence which has at least 75% identity to SEQ ID NO: 42.

Smith, S. *et al.* teach isolated pertussis toxin and filamentous hemagglutinin proteins from *Bordetella pertussis* (page 429, second column). The protein of Smith, S. *et al.* appears the same as the claimed polypeptide. Characteristics such as % identity and amino acid sequence would be inherent in the proteins of Smith, S. *et al.*

9. Since the office does not have the facilities for examining and comparing applicants' product(s) with the product(s) disclosed in the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product(s) and the product(s) of the prior art (*i.e.* that the product(s) of the prior art does not possess the same material structural and functional characteristics of the claimed product(s)). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald *et al.*, 205.

10. Claims 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith, S. *et al.* 1996. (J. Clin. Microbiol. 34(2): 429-430).

The claims are drawn to a method of diagnosing a *Bordetella pertussis* infection comprising identifying a polypeptide or an antibody specific to the polypeptide.

Smith, S. *et al.* teach identification of *Bordetella pertussis* infection in an adult comprising identifying antibodies specific for pertussis toxin and filamentous hemagglutinin (page 429). The method of Smith, S. *et al.* and the antibody are the same as the claimed method and antibody.

11. Since the office does not have the facilities for examining and comparing applicants' method(s) with the method(s) disclosed in the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed method(s) and the method(s) of the prior art (*i.e.* that the methods of the prior art does not possess the same material structural and functional characteristics of the claimed methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald *et al.*, 205.

12. Claims 72-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith, S. *et al.* 1996. (J. Clin. Microbiol. 34(2) : 429-430).

The claims are drawn to a kit comprising the polypeptide of SEQ ID NO: 42.

Smith, S. *et al.* teach proteins from filamentous hemagglutinin and pertussis toxin of *Bordetella pertussis* (page 429). The proteins of Smith, S. *et al.* appear the same as the claimed polypeptide. Characteristics such as amino acid sequence and % identity would be inherent in the proteins of Smith, S. *et al.*

13. Claims 33-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubenfield, M.J. *et al.* (US Patent 6,551,795 B1 published Apr. 22, 2003 with a prior filling date of Feb. 18, 1998).

The claims are drawn to polypeptide comprising a fragment of SEQ ID NO: 42 comprising an epitope, more specifically an immunogenic epitope.

Rubenfield, M.J. *et al.* teach an isolated polypeptide comprising a fragment of 9 amino acids of SEQ ID NO: 29960 with 100 % identity to instant SEQ ID NO: 42 amino acids 43-51(see GenCore result #1). Rubenfield, M.J. *et al.* further teach immunizing an animal wherein the immunogenic component comprises one or more of the polypeptides (inherently containing the fragment of SEQ ID NO: 42 that is immunogenic) at column 8, lines 52-42.

Thus, Rubenfield, M.J. *et al.* anticipates the instant claimed invention.

Status of the Claims

14. No claim allowed.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammy K. Field whose telephone number is (571) 272-0856. The examiner can normally be reached on Monday-Friday from 7am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (571) 272- 0864.

Papers relating to this application may be submitted to Technology Center 1600 Group 1640 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communications and After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov/. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tammy K. Field
May 15, 2004

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